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FOREWORD

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Donna C. Yakushev 11 October 1996
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INTRODUCTION

The main objective of this infrastructure project was to expand a population-based mammography registry to include every mammogram performed in practices in a 24 county area of North Carolina, which has a large rural, and black rural population. The goal is to link pathology data, mammography diagnostic data, outcome data and quality data to study the patterns of use of mammography, and the patterns of practice of mammography in this distinct geographic region.

Previous to this application, a mammographic data retrieval system had been developed by the investigators, and feasibility work performed to get it into practices outside of the academic medical center. The project was proposed for an area that was already organized for pathology retrieval for the Breast Cancer SPORE. Having the infrastructure in place would allow research on mammography outcomes, with the ability to compare women served by the CDC BCCCP program and to study differences between rural and urban, and black and white women.

WORK IN PROGRESS

Task 1: Organizational Development (0-6 months.)

- a. Create oversight committee: to set policy, definitions and time tables, and promotional guidance for registry.*
- b. Create executive committee for practice recruitment: to design outreach program, and publicity for recruitment.*
- c. Create executive committee for pathologist recruitment: to establish approach for pathologist recruitment.*

At the end of year 2, task 1 is completed. We have an advisory committee with the diversity of representation to accomplish all the above tasks. We call on their expertise when needed. We send them all staff meeting minutes to keep them abreast of what we are doing.

Task 2: Customize and install computer network and programs (0-12 months).

- a. Design and install computer interface and linking programs to enable linkage to Lineberger CCC and NC-CCR.*
- b. Establish confidentiality and quality control protocols*

In the first year, we developed systems for quality control checks of the data. At the end of year two these programs have been built into a computerized data management system, that automates much of this work. It logs in records, pulls in the data quality programs, it lists edit reports to send to the practice, and keeps track of edit returns. This has streamlined our process as we grow in number of practices reporting data to us.

Confidentiality of data has been a concern that we pay attention to at all times. In addition to the progress we reported last year, we have now received a Public Health Certificate of Confidentiality which protects data both at our Registry site, and gives us protection as we send the data across state lines to the National Breast Cancer Surveillance Consortium. We have taken a few extra steps that were not originally described. We now have practices assign their radiologists unique codes to identify themselves without telling us to whom the codes belong.

* Acronyms defined in Appendix.

The same codes get used for the same radiologists over time, but we have no need to know the name of the Radiologists, and do not have this information. We treat the technologists the same way. We have continuing conferences and discussions with all the staff. We have made an effort to keep the issues of confidentiality forever on the front burner, and in everyone's mind on a continuing basis. Our first publication from this project is a description of the procedures we follow for data quality and confidentiality of our data. The manuscript is attached.

We have worked out all procedures for linking the mammography database with the pathology database. We have created an in-house pathology database which is a compilation of pathology data we receive from three sources: 1) weekly fast reporting of all newly diagnosed breast cancer pathology data for the 24 counties; 2) the annual data for the state central cancer registry (we now have the annual data for 1994 and for 1995, unfortunately there is a lag in receiving this data); and 3) the pathology data that is entered into our mammography tracking system for the practices that follow their patients for pathology data. In addition we are now beginning to get benign pathology data for our pathology database, (described below). We have developed the same level of data quality checks and rules of confidentiality for the pathology data. We now have the ability to link mammographic data with this pathology database.

We have completed Task 2.

Task 3: Enroll Mammography practices and pathologists into registry (0-24 months)

- a. *Contact every mammography practice in 24 counties to enroll in registry*
- b. *Demonstrate and install mammography database in interested practices*
- c. *Arrange for data transfer in practices already using a data system*
- d. *Arrange for paper data collection and transfer in practices choosing this option.*
- e. *Establish process with each pathology site for acquisition of all breast pathology data:
and expand process with those already cooperating with NCCCR, to acquire benign breast pathology.*

As could be predicted, recruitment happened with a flurry as the more willing practices came up in the first year. We have had to work harder to get other practices to participate in the project. We have had quite a bit of success, it has just taken longer than we originally predicted. It was unrealistic to assume that I could get all facilities up in 24 months. However, we are making excellent progress. As of 1 October 1996 we have 53 facilities collecting data for the registry, representing 16 of our 24 counties, and 7 counties outside the 24 (one of which interprets for practices in the 24). We also have data on 2 sites in South Carolina. Table 1 which follows presents the practices now collecting data for the registry, the county, the date they started collecting data, and the status of records added to the registry and records in the edit process. A data batch is not entered into the registry until all the edit problems in that batch have been resolved.

Two of our largest screening facilities, an academic center and an HMO with three facilities have their own data systems. We have been working out a transfer process for ongoing transfer of their data to us. When they come on board, they will add 2 more sites and a large amount of data

per site. The academic center will be giving us their data back to January 1995. The HMO has just begun computerized data collection of mammography data, and we will only get prospective data.

Five of our practices have chosen to send us data on paper, and we enter their data on site at the Registry. This data goes through the same QA procedures as the computerized data.

Our data system has had many improvements over the past year. It is a full query installed now that allows practices to print custom reports from their data. It has easy to use standard reports for follow-up and tracking their positive mammograms. It also will link to pathology records if they enter pathology outcomes on site. We also are working on providing remote electronic transfer for the practices that would benefit from that. We have a test site up and working. This will save costs of mailing data and reports. It will also allow us to trouble shoot data systems remotely. We expect that about 10% of our practices may opt for this method of data transfer.

We have made good progress on access to the benign pathology data. Of the 28 pathology facilities, we now have 17 sending us benign data at the present time. Another 4 have committed to work with us. In most cases, we are getting data retroactive to 1 January 1995. Thus, though the process has been slower than we would have liked, we are not losing the earlier data. We are in communication with all the pathology facilities. In most of the cases, we are waiting for a review committee or IRB to give permission or are working out the details of how the transfer will take place. We are confident that we will have benign breast pathology from most all the facilities within the next 3 months. The NC Central Cancer Registry has been extremely helpful in this endeavor getting approval from their advisory committee for the NC-CCR to request this data for the CMR. They continue to aid us in working with the pathology facilities.

Task 4: Operate and Maintain Registry (0-36 months)

- a. On-going data cleaning and entry*
- b. On-going quality control*
- c. Linkage to NC-CCR and Lineberger CCC*
- d. Respond to requests for shared use of registry data (beginning at 36 months)*

We are operating much more smoothly than a year ago, with procedures automated, and many more practices sending data on a regular schedule. Our pathology database has been automated and linking is now possible. We now have the capability to begin data analysis. We have been able to service the radiology practices with special requests in preparation for their MQSA site visits. Though the practices have the ability in their software to create their own reports, many prefer that we handle this for them. This is a service we offer in exchange for their participation in the project. We are better suited to locate the pathology for their patients who do not get followed at their local sites.

Other Activities.

As we reported last year, we were successful in being funded by NCI to become members of the National Breast Cancer Surveillance Consortium. The Principal Investigator, Bonnie Yankaskas, is a member of the Steering Committee of the Consortium. The consortium has now agreed on

the core mammographic, pathologic and follow-up variables that we will collect for the national dataset. We were well poised to accomplish this with little extra work, as we had already designed a data collection system that is in line with the goals of the consortium. The consortium through its Statistical Coordinating Center will enhance our ability to strengthen any research we do by letting us compare results on a national scale. Several workgroups have been formed within the consortium for carrying out specific research projects. Again, this enhances any work we do with our data in NC. The NC data is the only population data with a large component of rural south and rural African American data.

As we begin the third and last year of this project, we are confident that we will have built an infrastructure of great quality and importance for research on community based screening mammography.

Status of Records into the Registry

	Practice Type	# of facilities (internal, external)*	County	Date Began	Records in registry	Records out for edit
1	Priv Pract Radiol	3 (1,2) both private medicine	Durham	Jul-93	24,045	1,072
2	Priv Ob/Gyn	1 (0) films read by 24	Pitt	Nov-93	0	7,144
3	Univ Hospital	1 (2,1) family practice	Orange	Jan-94	9,644	0
4	Priv Prac Radiol	7 (1,6) private ob/gyn	Guilford	Dec-94	19,585	0
		private family practice	New Hanover			
		private radiol	Johnston			
		private radiology	Alamance			
		private medicine	SC			
		private clinic	SC			
5	Hospital Radiol	1 (1, 0)	Yadkin	Jan-95	0	1,606
6	Priv Prac Radiol	2 (1, 1) private hospital	Beaufort	May-95	3,313	522
7	Hospital Radiol	1 (1, 0)	Moore	Jun-95	799	188
8	Hospital Radiol	1 (1, 0)	Nash	Jul-95	3,709	1,091
9	Hospital Radiol	1 (1, 0)	Bertie	Aug-95	0	504
10	Hospital Radiol	1 (1, 0)	Wayne	Aug-95	1,242	286
11	Hospital Radiol	5 (3, 2) private clinic	Mecklenburg	Sep-95	0	24,389
		2 private mobile	Mecklenburg			
12	Public Health Ctr	1 (1, 0)	Graham	Sep-95	173	0
13	Hospital Radiol	1 (1, 0)	Nash	Oct-95	495	0
14	Priv Medicine	1 (0) films read by 24	Pitt	Oct-95	2,722	526
15	Hospital	1 (0) films read by 24	Washington	Oct-95	0	313
16	Hospital Radiol	2 (1, 1) private ob/gyn	Wilson	Oct-95	932	1,133
17	Priv Prac Radiol	5 (1, 4) private radiol	Orange	Jan-96	0	1,319
		2 private medicine	Wake			
		private hospital	Johnston			
18	Hospital Radiol	2 (2, 0)	Alamance	Mar-96	0	0
19	Hospital Radiol	1 (1, 0)	Martin	Mar-96	226	207
20	Priv Pract Radiol	1 (1, 0)	Wake	Apr-96	0	527
21	Hospital Radiol	1 (1, 0)	Mitchell	Apr-96	0	843
22	Hospital Radiol	1 (1, 0)	Macon	Jul-96	0	0
23	Hospital Radiol	2 (2, 0)	Harnett	Jul-96	0	0
24	Priv Acad Hosp	5 (2, 3) private medicine	Pitt	Jul-96	0	737
		public hospital	Pitt			
		ob/gyn practice	Pitt			
25	Priv Prac Radiol	5 (2, 3) public health clinic	Wake	Jul-96	0	1,346
		private medicine	Wake			
		private hospital	Wake			
26	Hospital Radiol	1 (1,0)	Hertford	Oct-96	0	0
		53 (30, 23)	Total		66,885	43,753
			Grand total		110,638	
*internal-practice sites			counties in italics are outside			
external-read for other practices			of the 24-county study area			

The Carolina Mammography Registry.
Population-Based Mammography and Cancer Surveillance Project.

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Abstract

The linking of Central Cancer Registry data with population-based mammography data creates the potential to study screening mammography and outcomes from screening mammography in a defined population. In North Carolina, the Carolina Mammography Registry is being developed to capture all mammography performed in a defined population and linking these data with the North Carolina Central Cancer Registry for outcomes associated with the mammographic work-up. The combined data will be used to study the patterns of the practice of mammography, the accuracy of screening mammography on a population level, the experience of women in this population who have positive mammograms, and the cancer yield of screening mammography.

Introduction

Breast cancer is the second most commonly occurring cancer in women, and the second leading cause of death among women in the United States. It is estimated that in 1996 184,300 women will die from breast cancer.¹ The incidence in breast cancer has risen over the last decade, though mortality has remained relatively stable.²⁻⁴ One explanation for the increase in incidence has been the increase in-situ cancers and localized, small invasive cancers resulting from early detection by mammography screening. However, some argue that the more widespread screening does not fully account for the increase and many questions remain unanswered about the natural history of breast cancer. Because the lack of information about the etiology of breast malignancies make preventive measures difficult, public health efforts have emphasized early detection.⁵⁻⁸ Early diagnosis with screening mammography has been shown to reduce mortality in women over age 50, but the data on women in their forties is much less clear with trends toward risk reduction after eight to ten years.⁹⁻¹¹

Registries have been part of the national public health scene providing important public health information in many arenas, particularly in cancer surveillance. Though there have been mammography registries created, it is only recently that there has been an appreciation of the value of a national mammography data.¹² In 1994 the Department of Defense, through their breast cancer research program, funded the creation of several mammography databases including the Carolina Mammography Registry (CMR), to create an infrastructure of data that would provide the opportunity to better understand how mammography ultimately impacts upon women's health. The CMR has been

established to study a population of approximately 360,000 women in 24 counties in the eastern part of North Carolina. The goal of the project is to track every mammogram performed on all women residing in the 24 counties, to have data on the patterns of use of mammography by this population of women, the results of the screening mammograms, the workup process for positive mammograms, and ultimately the outcome. This surveillance data is possible for two major reasons: 1) this particular area of North Carolina has already been mobilized for breast cancer research, and 2) we have an excellent state cancer registry, the North Carolina Central Cancer Registry (NC-CCR), that is providing outcome data, with excellent cooperation from the pathologists serving this area. In addition to having breast cancer outcome, we will have information of benign outcomes that may help shed light on the non-cancerous mammographic findings that result in unnecessary biopsies in many women.

The 24 county study area has the potential for valuable collaborative investigations with other breast cancer studies in this location. Other projects active in this same population which complement this effort include: the Carolina Breast Cancer Study (CBCS), a large case-control study of breast cancer etiology with a joint epidemiology and molecular biology approach, funded under the Special Projects of Research Excellence in Breast Cancer (SPORE) through the Lineberger Comprehensive Cancer Center; the North Carolina Breast Cancer Screening Program (NC-BCSP, also funded by the breast cancer SPORE), an educational project aimed at increasing initial and repeat breast cancer screening rates among black women over age 50; the Breast and Cervical Cancer Control Program (BCCCP) funded by CDC, a statewide program that provides funds for access to

breast and cervical cancer screening to underserved women at or below 200% of the poverty level. Twenty to twenty-five percent of the women enrolled in BCCCP receive mammography services within the 24 county area of the CMR.

CMR will serve as an ongoing resource for further research concerning questions about the variation in patterns of use of mammography, the practice of mammography, and the effectiveness of mammography in this study population. The combined mammography and cancer registry data will also be linked to a biology project that will enable us to study the biological differences of cancers detected and missed by screening mammography. Tissue procured under the CBCS are being analyzed to determine if markers of proliferation, invasion and stromal-epithelial cell communication differ between screen detected cancers and interval cancers in the mammography population.. All these activities along with the other research in this population serve to further our understanding of the relationship of genetic and environmental factors to the etiology of breast cancer.

Study Population

The 24 county area has diversity in its economic, racial and geographic makeup. There is a particularly large rural African American population compared to most study areas doing similar research. Figure 1 is a map of the 24 counties included for capture for the Registry. Tables 1 and 2 displays the age, racial, and urban/rural distributions of the target population.

The Registry Data

The Mammography Data.

CMR is comprised of a mammography database and a pathology database. Each mammogram reported becomes a record in the mammography database. CMR has targeted 71 facilities in the 24 counties where mammography is performed. The actual number fluctuates as managed care causes changes in practice management. These include private and hospital-based radiology practices, obstetrics and gynecology, Internal Medicine and Family Practices, and other sites that offer mammography screening. Participating facilities provide information in several ways, but the data is standard across facilities. At the time of their mammogram, patients provide information about demographics, pertinent medical history, breast surgical history, family history, and breast symptoms. At the time of the exam, the mammography technologist provides data on the test being performed, and the radiologist records the mammographic findings and recommendations for continued work-up or follow-up. These data are all collected on one form. There are three ways this data gets to the Registry: 1) by using the Carolina Mammography Data System (CMDS), a computer data entry program designed by CMR to exactly match the prescribed data collection forms; 2) by sending paper data forms; or 3) by sending electronic data from data systems of their own choosing.

The CMDS is a database system that was initially developed by the Breast Imaging Section of the Department of Radiology at the University of North Carolina Hospitals (UNCH) to collect data for research use and clinical follow-up. This database was modified and improved in its use at UNC and at several community radiology practices in

different parts of the state. The data collection forms match the PC screens. CMDS used at the facility enables the practice to create reports of their practice activity, mammographic findings and recommendations on site. There is the ability to query the entire dataset created by the practice via the program. That data is accessible for their own administrative needs and for tracking follow-up, as required by the Mammography Quality Standards Act (MQSA). In addition, the CMDS has other built-in administrative functions including reminder system for patient call-back, and the ability to produce letters to the patients about their results.

Several large practices and health maintenance organizations have their own data systems but are able to download their data which can be interfaced with the CMDS. Small practices without access to or desire to own computer resources have collected information on the data sheets and then forwarded it to CMR where it is entered into the CMDS by research staff.

The Pathology Data

The pathology database is created from pathology outcome data that comes to the Registry in three ways. First, the practices that use the CMDS have the ability to enter pathology data into the program if they receive pathology follow-up themselves. Second, CMR receives weekly reporting of all new breast cancer cases that are reported to the NC-CCR under their fast report system that covers all new cases in the 24 counties in the study area. The third source of pathology data is the annual breast cancer data from the complete NC-CCR data base. This annual data is for the entire state and is the only way

to identify breast cancer diagnoses that occur outside the 24 counties. The three sources of pathology reports are combined to create the CMR pathology database. As of spring 1996, the fast report data system began including benign breast pathology in addition to the breast cancer pathology.

Quality control of the Data.

CMR has an extensive quality assurance program for the mammography and pathology data. Various methods at different steps are employed in the process of collecting, editing, and analyzing the data. During the data entry process, essential data is requested twice to reduce error in the original data entry. The program alerts the data entry person of internal inconsistencies, such as duplicate records with the same social security number, invalid dates of study or birth, or inconsistent mammography interpretation codes and follow-up recommendations. After the raw data has been received by the registry, quality control programs are run that flag records with duplications, missing records, inconsistent data, and implausible dates. Once these programs are run, written reports of data problems are sent back to the facilities for editing. The corrected data are returned to CMR, the data is edited and only at this point is the data added to the registry.

The pathology data is put through a similar quality check. We rely on the NC-CCR's own quality assurance practices for the validity of the data itself, and we run quality checks for data entry errors, missing data, inconsistencies and implausible data. Problems encountered are listed and sent back to the NC-CCR for editing. This process at CMR is beneficial to the CMR data and to the NC-CCR.

Protection and confidentiality of the data

A primary concern in the establishment of the CMR was protecting confidentiality of the data we would be receiving. It is well documented that delay in the diagnosis of breast cancer is one of the most common reasons for medical malpractice lawsuits in this country, and that missed diagnoses account for the largest category of radiology-related cases.¹³⁻¹⁵ There are several good reports in the literature that address the issues to consider in maintaining confidentiality in large linked databases.¹⁶⁻²⁰ Many steps have been and continue to be taken to guard the safe keeping of the data, and the identities of all the practitioners and patients involved. We protect data during collection, in transit, in storage, and during analysis.

Data Collection and Transit.

The radiologists and technologists are protected at the point of data collection. The Registry data has no linkable identifiers for these professionals. The practices assign their own professionals unique ID codes which are not known to the CMR. The reports we produce for the practices will use the codes which enables the practices to have practitioner specific feedback without CMR knowing the identity of these professionals. In addition, the practices are given a unique alpha-numeric identifier which is used to label any reports or disks for that practice. A file to link these codes to the practice names and addresses is kept under password protection on a remote server.

The computerized data system itself has an intrinsic mechanism for protecting the data, so that it cannot be intercepted and read without the CMDS application. Any transport of

data sheets, disks or reports to the practices from CMR are done by courier or private companies that maintain location of the package at all times. We recommend to all our facilities that they do likewise when sending anything to us.

The CMR participants and the data is also protected under the issuance of a Certificate of Confidentiality by the US Public Health Service, and is afforded the same protection that our NC-CCR data receives under state law.

Storage and Analysis

Once the disks or data sheets arrive at the Registry, they are recorded in logs and maintained in secure files. The data sheets are returned to the practices immediately after the data has been entered by CMR staff. The Registry does not keep original or copies of any data sheets. We have disks and keep them in a locked, fireproof file. Once the data has been through the editing process and entered into the Registry, the data is only accessible from a remote server that can only be accessed by permission. This server requires a password accessible only to CMR employees, and no data is stored on any other drive that might be accessed by an unauthorized third party.

Prior to adding the mammography data from a facility to the Registry, a unique ID program is run which removes patient identifying and location information from the records, replacing these data with a unique ID by CMR. The file containing the mapping of unique identifiers is stored electronically in a password protected, encrypted file kept in a locked filing cabinet. The records with the unique ID and no other identifying

information are then added to the CMR database. Obviously, to link with the pathology information from the NC-CCR, the unique ID file must be linked back with the identifying information. This is the only purpose for which records are linked and it is a temporary linking. Data is never stored in linked fashion. Once a match is found, the appropriate unique ID is assigned to the pathology file and in a similar fashion, identifying information is removed. All analyses are performed on the file with the unique ID's for linking. There is no identification information in the datasets that are used for analysis.

CMR and NC-CCR Collaboration

The performance of breast cancer screening on a population basis is only possible where mammography data can be linked with population-based cancer registries. There is good data now that demonstrates the benefit on breast cancer mortality from screening mammography in women 50 and over. Yet, breast cancer continues to plague women of all ages, races and locations. If the full benefit of screening is to be realized, information on how mammography is used, by whom it is used, and the variation in outcomes needs to be evaluated on a large scale. It is only because of the collaboration of the NC-CCR and the CMR that this research is possible. The cooperation of the communities of practitioners is vital to this undertaking. With an established well-respected cancer registry already in place, the work of enrolling participants was facilitated. The joining of mammography data with central cancer data creates the opportunity to evaluate screening mammography on a population basis, with near complete outcome data. This enables us to have a population perspective on studying accuracy of the screening process, the

patterns of the workup after a positive screening mammogram and the costs of screening mammography. This will be valuable in helping form a rational public health plan.

National Breast Cancer Surveillance Consortium

Under funding from the National Cancer Institute, CMR is part of a national consortium of similar projects which will pool data creating a national database for research across regions and populations of the United States. The Consortium will have combined data for populations from the states of Washington, California, New Mexico, Colorado, Iowa, Vermont, New Hampshire and North Carolina. The Consortium has agreed upon data which will be core across projects, defined and collected in the same manner. All the projects in the Consortium are linked with their regional population-based cancer registries. This extends the potential for the CMR data in the breast cancer surveillance effort.

Future of the CMR

The Registry is now in its second year. At the end of the second year, preliminary analyses will begin. Getting all mammography facilities in 24 counties to participate has been a monumental task, and it is nearing completion. The data collection process will continue at least through the year 2000. At the end of 1997 we will have accrued sufficient follow-up time to have the follow-up data necessary for most analyses. The CMR data will be available for investigators to use for appropriate research. Like the NC-CCR which has been a gold mine for cancer research state-wide, it is our hope that the extension of the NC-CCR to its association with the CMR will create new

opportunities for valuable research which will have a positive outcome for detection and treatment of breast cancer in the future.

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Table 1: Distribution of Women 40 years and older in 24 county study area, by age and race.

<u>Age Group</u>	<u>White</u>		<u>Non-White</u>		<u>Total</u>
	n	%	n	%	
40-49	87,128	32	30,767	33	117,895
50-64	90,919	33	31,223	33	122,142
65-79	71,235	26	24,369	26	95,604
>= 80	23,953	9	7,101	8	31,054
Total	273,235	100	93,460	100	366,695

**Table 2: Distribution of Women 40 years and older in 24 county study area,
by race and urban/rural residence.**

<u>Residence</u>	<u>White</u>		<u>Non-White</u>		<u>Total</u>
	n	%	n	%	n
Rural	95,334	35	31,179	33	126,513
Urban	176,085	65	62,281	67	238,366
Total	271,419	100	93,460	100	364,879

[illegible]

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